# *Quality System* Documents

(Quality Manual and Related Procedures, Policies, & Objectives)

## Introduction:

For your laboratory to become certified by the State of Utah for environmental testing, your laboratory must provide the Utah Environmental Laboratory Certification Program (ELCP) with sufficient documentation describing the implementation of its ***quality system*** through construction of appropriate policy statements and procedure details.

## Regulatory Premise (NELAC, Chapter 5, 7/99):

### 5.5.1 Establishment

The laboratory shall **establish** and **maintain** a ***quality system*** based on the required elements contained in this chapter and appropriate to the type, range and volume of environmental testing activities it undertakes.

a) The elements of this ***Quality System*** **shall be documented in the organizations Quality Manual**.

b) The quality documentation shall be available for use by the laboratory personnel.

c) The laboratory shall **define and document** its **policies and objectives** for, and its commitment to accepted laboratory practices and quality of testing services.

d) The laboratory management shall ensure that these **policies** and **objectives** are **documented in a quality manual and** communicated to, understood, and implemented by all laboratory personnel concerned.

e) The quality manual shall be maintained current under the responsibility of the quality assurance officer.

### 5.5.2 Quality Manual

**The quality manual, and related quality documentation, shall state the laboratory's Policies and Operational Procedures established in order to meet the requirements of this Standard.**

# Guidance for *Quality Manual* Development:

*The following suggestion may be useful for laboratories needing to develop a Quality Manual & related procedures from the beginning, or for those who have identified a need for numerous revisions in their current documents.*

*Many standards from Chapter 5 of the NELAC manual (7/99) can be transformed into appropriate policy(objective) statements for your Quality Manual, followed with supplemental descriptions or procedure references as needed. Then, further describe in the Quality Manual, or related procedure, how the standard is achieved and documented in the laboratory.*

*To convert a standard into a policy statement for your Quality Manual, transform the standard grammatically into a statement of intent or action. Example: replace the words, "shall" & "must", with the word, "will". Also, replace the words, "the laboratory" with the name of your laboratory. Employ a similar approach to other sentences, and incorporate additional structural and wording modifications to accommodate how your laboratory specifically addresses each standard*.

# Required Components for the Quality Manual:

## 5.5.2 Quality Manual

The **quality manual** shall list on the title page

* a **document title**;
* the **laboratory's full name** and **address**;
* the **name, address** (if different from above), and **telephone number of individual(s) responsible for the laboratory**;
* the **name** of the **quality assurance officer** (however named);
* the identification of **all major organizational units** which are to be **covered by this quality manual** and
* the **effective date of the version**;

## 5.5.2 Quality Manual

The **quality manual** and related quality documentation shall also contain:

d) procedures to ensure that all records required under this Chapter are retained, as well as procedures for control and maintenance of documentation through a **document control system** which ensures that all standard operating procedures, manuals, or documents clearly **indicate** the **time period** during which the procedure or **document was in force**;

f) identification of the laboratory's **approved signatories**; at a minimum, **the title page of the Quality Manual must have the signed and dated concurrence**, (with appropriate titles) of all **responsible parties** including the **QA officer(s)**, **technical director(s)**, and the **agent who is in charge of all laboratory activities** such as the laboratory director or laboratory manager;

w) a Table of Contents, and applicable lists of references and glossaries, and appendices.

# ELCP Information Request:

The laboratory's format and arrangement for the Quality Manual and related procedures is at the laboratory's discretion. To facilitate this flexibility, the Utah ELCP is requesting that your laboratory **provide a cross reference** from the laboratory's **Quality Systems documents (Quality Manual, procedures, etc.)** for **each** required **element** as described in section **5.5.2 of the NELAC Standard (7/99).**

In this information request form, you will find each required ***element*** from section 5.5.2 of the NELAC standard in a **box with a heavy border**. The Quality Manual ***elements*** are positioned above each applicable **chapter 5 sub-section** from the NELAC Standard, and in other locations throughout the Standard. Following the elements you will find a list of related standards that more fully explain and aid in the self-evaluation of your laboratory's Quality System documents. The Laboratory's Quality System documents must **substantially and thoroughly address all applicable NELAC standards** listed in this document.

Using the document location reference(s) provided by your laboratory, your assigned surveyor(s) will review how the standards are implemented throughout the laboratory via its Quality Manual and/or procedure*(s)*. Your surveyor will attempt to verify that the ***standard***s listed below a given ***element*** are adequately addressed within the laboratory's *quality system* documents.

# Instructions:

Please **indicate** below:

* Laboratory Name:

* *Quality Manual* Revision Date:

* *Quality System* Assessment Performed by (Name & Title):

Please **provide** the ELCP with a **copy of** the laboratory's **Quality Manual** upon which the laboratory's self assessment is based. The Quality Manual provided to the ELCP must contain the required components described on page 2.

Please **provide** the ELCP with a **copy of** any separate **procedure(s) referenced** in the completed forms.

In the **boxes** provided (**heavy borders**), please **describe** a complete, and **specific reference(s) for each required element** from section 5.5.2 of the NELAC Standard. Please ***return this completed information request form*** to the ELCP ***with the application for certification***.

NOTE: To allow rapid associations throughout the survey process, please specify the page #, section #, subsection # , paragraph #, etc., of the Quality Manual or related procedure(s) as appropriate. Non-applicable items should be marked, " N/A" .

Where a ***standar*d** listed below an *element* **is not fully addressed under the cited reference**, a **separate reference** should be provided (left column) indicating where the specific standard is fully addressed.

NOTE: In such cases, failure to provide a substitute or supplementary reference for the individual standard may lead the ELCP to conclude that your laboratory has not addressed the standard within its *quality system* documents.

# Organization and Management;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall contain:<br><br>a) a **quality policy statement**, including **objectives**, and **commitments**, by top management;<br><br>b) the **organization** and **management structure** of the laboratory, its place in any parent organization and relevant **organizational charts**;<br><br>c) the **relationship** between **managemen**t, **technical operations**, **support services** and the **quality system**<br><br>e) **job descriptions** of key staff and reference to the job descriptions of other staff; |

**5.4.1 Legal Definition of Laboratory**

The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Standard.

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**5.4.2 Organization**
The laboratory shall:

a) have **managerial** staff with the **authority** and **resources** needed to discharge their duties;

b) have processes to ensure that its personnel are **free from** any **commercial, financial** and **other undue pressures** which might adversely affect the quality of their work;

c) be organized in such a way that confidence in its **independence of judgmen**t and **integrity** is **maintained** at all times;

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**5.4.2 Organization**
The laboratory shall:

d) specify and document the **responsibility**, **authority**, and **interrelationship** of all **personnel** who manage, perform or verify work affecting the quality of calibrations and tests;

Such documentation shall include:

1) a clear description of the **lines of responsibility** in the laboratory and shall be **proportioned** such that **adequate supervision is ensured** and

2) **job descriptions** for all positions.

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**5.4.2 Organization**
The laboratory shall:

e) provide **supervision** by **persons familiar** with the calibration or **test methods** and **procedures**, the objective of the **calibration** or test and the **assessment of the results**;

e) The **ratio of supervisory** to non-supervisory personnel shall be such as to **ensure adequate supervision** to **ensure adherence** to laboratory **procedures** and accepted techniques.

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**5.4.2 Organization**
The laboratory shall:

f) have a **technical director(s)** (however named) who **has overall responsibility** for the **technical operation** of the environmental testing laboratory;

f) The **technical director(s)** shall **certify** that personnel with appropriate educational and/or technical background perform all tests for which the laboratory is accredited. Such **certification** shall be **documented**.

f) The **technical director**(s) shall meet the **requirements** specified in the Accreditation Process. (see 4.1.1.1)

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**5.4.2 Organization**
The laboratory shall:

g) have a **quality assurance officer** (however named) who **has responsibility** for the **quality system and its implementation**;

g) The **quality assurance officer** shall have **direct access** to the **highest level of management** at which decisions are taken on laboratory policy or resources, and to the **technical director**.

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**5.4.2 Organization**
g) The **quality assurance officer** (and/or his/her designees) shall:

1) serve as the focal point for QA/QC and be **responsible** for the **oversight** and/or **review** of **quality control data**;

2) have functions **independen**t from **laboratory operations** for which they have quality assurance oversight;

3) be able to **evaluate data objectively** and **perform assessments <u>without outside (e.g., managerial) influence</u>**;

4) have **documented training** and/or **experience** in **QA/QC procedures** and be **knowledgeable** in the **quality system** as defined under NELAC;

5) have a general **knowledge** of the **analytical test methods** for which data review is performed;

6) **arrange** for or **conduct internal audits** on the **entire technical operation annually**; and,

7) **notify laboratory management** of **deficiencies** in the **quality system** and **monitor corrective action**.

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**5.4.2 Organization**
The laboratory shall:

h) **nominate deputies** in case of **absence** of the **technical director(s)** and/or **quality**

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**5.4.2 Organization**
The laboratory shall:

i) have documented policy and procedures to ensure the protection of clients' confidential information and proprietary rights (this may not apply to in-house laboratories);

**5.4.2 Organization**
The laboratory shall:

j) when available, participate in inter-laboratory comparisons and proficiency testing programs. For purposes of qualifying for and maintaining accreditation, each laboratory shall **participate** in a **proficiency test program** as outlined in Chapter Two.

# Quality System - Establishment, Audits, Essential Quality Controls and Data Verification;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>a) a **quality policy statement**, including **objectives**, and **commitments**, by top management; |

**5.5.1 Establishment** The laboratory shall establish and maintain a quality system based on the required elements contained in this chapter and appropriate to the type, range and volume of environmental testing activities it undertakes.

a) The elements of this quality system shall be documented in the organizations quality manual.

b) The quality documentation shall be available for use by the laboratory personnel.

c) The laboratory shall define and document its policies and objectives for, and its commitment to accepted laboratory practices and quality of testing services.

d) The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned.

e) The quality manual shall be maintained current under the responsibility of the quality assurance officer.

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**5.5.2 Quality Manual**

The quality manual, and related quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Standard.

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>s) procedures for **audits** and data review; |

**5.5.3 Audits, Reviews and Corrective Actions**
**5.5.3.1 Internal Audits**

The laboratory shall arrange for annual internal audits to verify that its operations continue to comply with the requirements of the laboratory's quality system. It is the responsibility of the quality assurance officer to plan and organize audits as required by a predetermined schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit will be carried out. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibrations or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

#### 5.5.3.2 Managerial Review

The laboratory management shall conduct a review, at least annually, of its quality system and its testing and calibration activities to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements in the quality system and laboratory operations. The review shall take account of reports from managerial and supervisory personnel, the outcome of recent internal audits, assessments by external bodies, the results of interlaboratory comparisons or proficiency tests, any changes in the volume and type of work undertaken, feedback from clients, corrective actions and other relevant factors. The laboratory shall have a procedure for review by management and maintain records of review findings and actions.

#### 5.5.3.3 Audit Review

All audit and review findings and any corrective actions that arise from them shall be documented. The laboratory management shall ensure that these actions are discharged within the agreed time frame as indicated in the quality manual and/or SOPs

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>n) reference to verification practices including interlaboratory comparisons, **proficiency testing** programs, use of reference materials and internal quality control schemes; |

#### 5.5.3.4 Performance Audits

In addition to periodic audits, the laboratory shall ensure the quality of results provided to clients by implementing checks to monitor the quality of the laboratory's analytical activities.

Examples of such checks are:

a) internal quality control procedures using whenever possible statistical techniques; (see 5.5.4 below)

b) participation in proficiency testing or other interlaboratory comparisons (See Chapter Two);

c) use of certified reference materials and/or in-house quality control using secondary reference materials as specified in Section 5.5.4;

d) replicate testings using the same or different test methods;

e) re-testing of retained samples;

f) correlation of results for different parameters of a sample (for example, total phosphorus should be greater than or equal to orthophosphate).

**5.5.2 Quality Manual**

The quality manual and related quality documentation shall also contain:

o) procedures to be followed for feedback and **corrective action** whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

**5.5.3.5 Corrective Actions**

a) In addition to providing acceptance criteria and specific protocols for corrective actions in the Method Standard Operating Procedures (see 5.10.1.1), the laboratory shall implement general procedures to be followed to determine when departures from documented policies, procedures and quality control have occurred. These procedures shall include but are not limited to the following:

1) identify the individual(s) responsible for assessing each QC data type;

2) identify the individual(s) responsible for initiating and/or recommending corrective

3) define how the analyst should treat a data set if the associated QC measurements

4) specify how out-of-control situations and subsequent corrective actions are to be

5) specify procedures for management (including the QA officer) to review corrective

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**5.5.3.5 Corrective Actions**

b) To the extent possible, samples shall be reported only if all quality control measures are acceptable. If a quality control measure is found to be out of control, and the data is to be reported, all samples associated with the failed quality control measure shall be reported with the appropriate data qualifier(s).

**5.5.2 Quality Manual**

The quality manual and related quality documentation shall also contain:

n) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials and internal **quality control schemes**;

**5.5.4 Essential Quality Control Procedures**

These general quality control principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (i.e., chemical, whole effluent toxicity, microbiological, radiological, air) and are further described in Appendix D. The standards for any given test type shall assure that the applicable principles are addressed:

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**5.5.4 Essential Quality Control Procedures**

a) All laboratories shall have detailed written protocols in place to monitor the following quality

1) Adequate positive and negative controls to monitor tests such as blanks, spikes, reference toxicants;

2) Adequate tests to define the variability and/or repeatability of the laboratory results such as replicates;

3) Measures to assure the accuracy of the test method including sufficient calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;

4) Measures to evaluate test method capability, such as detection limits and quantitation limits or range of applicability such as linearity;

5) Selection of appropriate formulae to reduce raw data to final results such as regression analysis, comparison to internal/external standard calculations, and statistical analyses;

6) Selection and use of reagents and standards of appropriate quality;

7) Measures to assure the selectivity of the test for its intended purpose; and

8) Measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the test method such as temperature, humidity, light, or specific instrument conditions.

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**5.5.4 Essential Quality Control Procedures**

b) All quality control measures shall be assessed and evaluated on an on-going basis, and quality control acceptance criteria shall be used to determine the usability of the data. (See Appendix D.)

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**5.5.4 Essential Quality Control Procedures**

c) The laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exist. (See 5.11.2, Sample Acceptance Policy.)

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**5.5.4 Essential Quality Control Procedures**

d) The quality control protocols specified by the laboratory's method manual (5.10.1.2) shall be followed. The laboratory shall ensure that the essential standards outlined in Appendix D, or mandated methods or regulations (which ever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent the QC in the mandated method or regulations is to be followed. The essential quality control measures for testing are found in Appendix D of this Chapter.

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# Personnel;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>t) **processes/procedures** for establishing that personnel are adequately experienced in the duties they are expected to carry out and are receiving any needed **training**;<br><br>d) procedures to ensure that all **records** required under this Chapter are **retained**, as well as procedures for control and maintenance of documentation through a document control system which ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force;<br><br>u) processes/procedures for **educating** and **training** personnel in their ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions; |

**5.6.1 General Requirements for Laboratory Staff**

The laboratory shall have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions.

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**5.6.1 General Requirements for Laboratory Staff**

All personnel shall be responsible for complying with all quality assurance/quality control requirements that pertain to their organizational/technical function. Each technical staff member must have a combination of experience and education to adequately demonstrate a specific knowledge of their particular function and a general knowledge of laboratory operations, test methods, quality assurance/quality control procedures and records management.

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**5.6.2 Laboratory Management Responsibilities**
In addition to 5.4.2.d, the laboratory management shall be responsible for:

a) Defining the minimal level of qualification, experience and skills necessary for all positions in the laboratory. In addition to education and/or experience, basic laboratory skills such as using a balance, colony counting, aseptic or quantitative techniques shall be considered;

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**5.6.2 Laboratory Management Responsibilities**
In addition to 5.4.2.d, the laboratory management shall be responsible for:

b) Ensuring that all technical laboratory staff have demonstrated capability in the activities for which they are responsible. Such demonstration shall be documented. (See Appendix C); Note: In laboratories with specialized A work cells (a well defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration must be fully documented.

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**5.6.2 Laboratory Management Responsibilities**
In addition to 5.4.2.d, the laboratory management shall be responsible for:

c) Ensuring that the training of each member of the technical staff is kept up-to-date (on-going)

1) Evidence must be on file that demonstrates that each employee has read, understood, and is using the latest version of the laboratory's in-house quality documentation, which relates to his/her job responsibilities.

2) Training courses or workshops on specific equipment, analytical techniques or laboratory procedures shall all be documented.

3) Training courses in ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions. Evidence must also be on file which demonstrates that each employee has read, acknowledged and understood their personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.

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**5.6.2 Laboratory Management Responsibilities**
In addition to 5.4.2.d, the laboratory management shall be responsible for:

c) Ensuring that the training of each member of the technical staff is kept up-to-date (on-going)

4) Analyst training shall be considered up to date if an employee training file contains a certification that technical personnel have read, understood and agreed to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year:

I. Acceptable performance of a blind sample (single blind to the analyst);
ii. Another demonstration of capability;
iii. Successful analysis of a blind performance sample on a similar test method using the same technology (e.g., GC/MS volatiles by purge and trap for Methods 524.2, 624 or 5035/8260) would only require documentation for one of the test methods;
iv. At least four consecutive laboratory control samples with acceptable levels of precision and accuracy;
v. If I-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable results.

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**5.6.2 Laboratory Management Responsibilities**
In addition to 5.4.2.d, the laboratory **management shall be responsible** for:

d) **Documenting all analytical and operational activities** of the laboratory;

e) **Supervising all personnel** employed by the laboratory;

f) **Ensuring** that all **sample acceptance criteria** (Section 5.11) are **verified** and that samples are logged into the sample tracking system and properly labeled and stored;

g) **Documenting the quality** of all **data reported** by the laboratory; and

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**5.6.2 Laboratory Management Responsibilities**

In addition to 5.4.2.d, the laboratory management shall be responsible for:

h) Developing a proactive program for prevention and detection of improper, unethical or illegal actions. Components of this program could include: internal proficiency testing (single and double blind); post-analysis, electronic data and magnetic tape audits; effective reward program to improve employee vigilance and co-monitoring; and separate SOPs identifying appropriate and inappropriate laboratory and instrument manipulation practices.

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**5.6.3 Records**

Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained by the laboratory [see 5.6.2.c], including records on demonstrated proficiency for each laboratory test method, such as the criteria outlined in 5.10.2.1 for chemical testing.

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# Physical Facilities - Accommodation and Environment;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>l) mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate **facilities and resources** before commencing such work;<br><br>l) reference to the major equipment and reference measurement standards used as well as the **facilities** and services used by the laboratory in conducting tests; |

**5.7.1 Environment**

a) Laboratory accommodation, test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of tests.

b) The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

c) The laboratory shall provide for the effective monitoring, control and recording of environmental conditions as appropriate. Such environmental conditions may include biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels .

d) In instances where monitoring or control of any of the above mentioned items are specified in a test method or by regulation, the laboratory shall meet and document adherence to the laboratory facility requirements.

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**5.7.2 Work Areas**

a) There shall be effective separation between neighboring areas when the activities therein are incompatible including culture handling or incubation areas and volatile organic chemicals handling areas.

b) Access to and use of all areas affecting the quality of these activities shall be defined and controlled.

c) Adequate measures shall be taken to ensure good housekeeping in the laboratory and to ensure that any contamination does not adversely affect data quality.

d) Work spaces must be available to ensure an unencumbered work area. Work areas include:

1) access and entryways to the laboratory;
2) sample receipt area(s);
3) sample storage area(s);
4) chemical and waste storage area(s); and,
5) data handling and storage area(s).

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# Equipment and Reference Materials;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>l) reference to the major **equipment** and **reference measurement** standards used as well as the facilities and services used by the laboratory in conducting tests;<br><br>m) reference to procedures for calibration, verification and **maintenance of equipment;**<br><br>n) reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of **reference materials** and internal quality control schemes;<br><br>g) the laboratory's procedures for achieving **traceability of measurements**; |

**5.8 EQUIPMENT AND REFERENCE MATERIALS**

a) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of tests for which accreditation is sought. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Standard are met.

b) All equipment shall be properly maintained, inspected and cleaned. Maintenance procedures shall be documented.

c) Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

d) Each item of equipment including reference materials shall, when appropriate, be labeled, marked or otherwise identified to indicate its calibration status.

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**5.8 EQUIPMENT AND REFERENCE MATERIALS**

e) Records shall be maintained of each major item of equipment and all reference materials significant to the tests performed. These records shall include documentation on all routine and non-routine maintenance activities and reference material verifications. The records shall include:

1) the name of the item of equipment;
2) the manufacturer's name, type identification, and serial number or other unique identification;
3) date received and date placed in service (if available);
4) current location, where appropriate;
5) if available, condition when received (e.g. new, used, reconditioned);
6) copy of the manufacturer's instructions, where available;
7) dates and results of calibrations and/or verifications and date of the next calibration and/or verification;
8) details of maintenance carried out to date and planned for the future; and,
9) history of any damage, malfunction, modification or repair.

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# Measurement Traceability and Calibration;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>g) the laboratory's **procedures** for achieving **traceability of measurements**;<br><br>j) reference to the **calibration and/or verification test procedures** used;<br><br>m) reference to **procedures for calibration, verification** and maintenance of equipment; |

**5.9.1 General Requirements**

All measuring operations and testing equipment having an effect on the accuracy or validity of tests shall be calibrated and/or verified before being put into service and on a continuing basis. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment. This includes balances, thermometers and control standards.

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**5.9.2 Traceability of Calibration**

a) The overall program of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that measurements made by the laboratory are traceable to national standards of measurement where available.

b) Calibration certificates, when available, shall indicate the traceability to national standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified meteorological specification. The laboratory shall maintain records of all such certifications.

c) Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable program of interlaboratory comparisons, proficiency testing, or independent analysis.

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**5.9.3 Reference Standards**

a) Reference standards of measurement held by the laboratory (such as Class S or equivalent weights or traceable thermometers) shall be used for calibration only and for no other purpose, unless it can be demonstrated that their performance as reference standards have not been invalidated. Reference standards of measurement shall be calibrated by a body that can provide, where possible, traceability to a national standard of measurement.

b) There shall be a program of calibration and verification for reference standards.

c) Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications. Reference materials shall, where possible, be traceable to national or international standards of measurement, or to national or international standard reference materials.

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**5.9.4 Calibration**

Calibration requirements are divided into two parts: (1) requirements for analytical support equipment, and 2) requirements for instrument calibration. In addition, the requirements for instrument calibration are divided into initial instrument calibration and continuing instrument calibration verification.

**5.9.4.1 Support Equipment**

These standards apply to all devices that may not be the actual test instrument, but are necessary to support laboratory operations. These include but are not limited to: balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices (including thermometers and thermistors), thermal/pressure sample preparation devices and volumetric dispensing devices (such as Eppendorf, or automatic dilutor/dispensing devices) if quantitative results are dependent on their accuracy, as in standard preparation and dispensing or dilution into a specified volume.

All support equipment shall be:

a) Maintained in proper working order. The records of all repair and maintenance activities including service calls, shall be kept.

b) Calibrated or verified at least annually, using NIST traceable references when available, over the entire range of use.

The results of such calibration shall be within the specifications required of the application for which this equipment is used or:

1) The equipment shall be removed from service until repaired; or
2) The laboratory shall maintain records of established correction factors to correct all measurements.

c) Raw data records shall be retained to document equipment performance.

d) Prior to use on each working day, balances, ovens, refrigerators, freezers, incubators and water baths shall be checked with NIST traceable references (where possible) in the expected use range. Additional monitoring as prescribed by the test method shall be performed for any device that is used in a critical test (such as incubators or water baths). The acceptability for use or continued use shall be according to the needs of the analysis or application for which the equipment is being used.

e) Mechanical volumetric dispensing devices (except Class A glassware) shall be checked for accuracy on at least a quarterly use basis. Glass microliter syringes are to be considered in the same manner as Class A glassware, but must come with a certificate attesting to established accuracy or the accuracy must be initially demonstrated and documented by the laboratory.

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**5.9.4.1 Support Equipment**

3) For chemical tests the temperature, cycle time, and pressure of each run of autoclaves must be documented by the use of appropriate chemical indicators or temperature recorders and pressure gauges.

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**5.9.4.1 Support Equipment**

4) For biological tests that employ autoclave sterilization see section D.3.8.

**5.9.4.2 Instrument Calibration:**

This standard specifies the essential elements that will define the procedures and documentation for initial instrument calibration and continuing instrument calibration verification to ensure that the data will be of known quality and be appropriate for a given regulation or decision. This standard does not specify detailed procedural steps (how to) for calibration, but establishes the essential elements for selection of the appropriate technique(s). This approach allows flexibility and permits the employment of a wide variety of analytical procedures and statistical approaches currently applicable for calibration. If more stringent standards or requirements are included in a mandated test method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not apparent which standard is more stringent, then the requirements of the regulation or mandated test method are to be followed.

Note: In the following sections, initial instrument calibration is directly used for quantitation and continuing instrument calibration verification is used to confirm the continued validity of the initial calibration.

**5.9.4.2.1 Initial Instrument Calibration:**
The following items are essential elements of initial instrument calibration:

a) The details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria and associated statistics must be included or referenced in the test method SOP. When initial instrument calibration procedures are referenced in the test method, then the referenced material must be retained by the laboratory and be available for review.

b) Sufficient raw data records must be retained to permit reconstruction of the initial instrument calibration, e.g., calibration date, test method, instrument, analysis date, each analyte name, analyst's initials or signature; concentration and response, calibration curve or response factor.

c) Sample results must be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification.

d) All initial instrument calibrations must be verified with a standard obtained from a second source and traceable to a national standard, when available.

e) Criteria for the acceptance of an initial instrument calibration must be established, e.g., correlation coefficient or relative percent difference.

f) Results of samples not bracketed by initial instrument calibration standards (within calibration range) must be reported as having less certainty, e.g., defined qualifiers or flags or explained in the case narrative. The lowest calibration standard must be above the detection limit.

g) If the initial instrument calibration results are outside established acceptance criteria, corrective actions must be performed. Data associated with an unacceptable initial instrument calibration shall not be reported.

h) Calibration standards must include concentrations at or below the regulatory limit/decision level, if these limits/levels are known by the laboratory, unless these concentrations are below the laboratory's demonstrated detection limits (See D.1.4 Detection Limits)

i) If a reference or mandated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. The laboratory must have a standard operating procedure for determining the number of points for establishing the initial instrument calibration.

**5.9.4.2.2 Continuing Instrument Calibration Verification**

When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration verification with each analytical batch. The following items are essential elements of continuing instrument calibration verification:

**5.9.4.2.2 Continuing Instrument Calibration Verification**
The following items are essential elements of continuing instrument calibration verification:

a) The details of the continuing instrument calibration procedure, calculations and associated statistics must be included or referenced in the test method SOP.

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**5.9.4.2.2 Continuing Instrument Calibration Verification**
The following items are essential elements of continuing instrument calibration verification:

b) A continuing instrument calibration verification must be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range. If an internal standard is used, only one continuing instrument calibration verification must be analyzed per analytical batch.

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**5.9.4.2.2 Continuing Instrument Calibration Verification**
The following items are essential elements of continuing instrument calibration verification:

c) Sufficient raw data records must be retained to permit reconstruction of the continuing instrument calibration verification, e.g., test method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations. Continuing calibration verification records must explicitly connect the continuing verification data to the initial instrument calibration.

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**5.9.4.2.2 Continuing Instrument Calibration Verification**
The following items are essential elements of continuing instrument calibration verification:

d) Criteria for the acceptance of a continuing instrument calibration verification must be established, e.g., relative percent difference.

e) If the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions must be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptance criteria, then either the laboratory has to demonstrate performance after corrective action with two consecutive successful calibration verifications, or a new initial instrument calibration must be performed. If the laboratory has not demonstrated acceptable performance, sample analyses shall not occur until a new initial calibration curve is established and verified. However, sample data associated with an unacceptable calibration verification may be reported as qualified data under the following special conditions:

   i) When the acceptance criteria for the continuing calibration verification are exceeded high, i.e., high bias, and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

   ii. When the acceptance criteria for the continuing calibration verification are exceeded low, i.e., low bias, those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be reanalyzed after a new calibration curve has been established, evaluated and accepted.

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# Test Methods and Standard Operating Procedures;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>h) a **list of all test methods** under which the laboratory performs its accredited testing;<br><br>p) the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;<br><br>v) reference to **procedures** for **reporting analytical results**; and,<br><br>g) the laboratory's **procedures** for achieving **traceability of measurements**; |

**5.10.1 Methods Documentation**

a) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests.

b) All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

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**5.10.1.1 Standard Operating Procedures (SOPs)**

Laboratories shall maintain standard operating procedures that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods.

a) These documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents.

b) The test methods may be copies of published methods as long as any changes in the methods are documented and included in the methods manual (see 5.10.1.2).

c) Copies of all SOPs shall be accessible to all personnel.

d) The SOPs shall be organized .

e) Each SOP shall clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority.

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**5.10.1.2 Laboratory Method Manual(s)**

a) The laboratory shall have and maintain an in-house methods manual(s) for each accredited analyte or test method.

b) This manual may consist of copies of published or referenced test methods or standard operating procedures that have been written by the laboratory. In cases where modifications to the published method have been made by the laboratory or where the referenced test method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each test method shall include or reference where applicable:

1) identification of the test method;

2) applicable matrix or matrices;

3) detection limit;

4) scope and application, including components to be analyzed;

5) summary of the test method;

6) definitions;

7) interferences;

8) safety;

9) equipment and supplies;

10) reagents and standards;

11) sample collection, preservation, shipment and storage;

12) quality control;

13) calibration and standardization;

14) procedure;

15) calculations;

16) method performance;

17) pollution prevention;

18) data assessment and acceptance criteria for quality control measures;

19) corrective actions for out-of-control data;

20) contingencies for handling out-of-control or unacceptable data;

21) waste management;

22) references; and,

23) any tables, diagrams, flowcharts and validation data.

### 5.10.2 Test Methods

a) The laboratory shall use appropriate test methods and procedures for all tests and related activities within its responsibility (including sample collection, sample handling, transport and storage, sample preparation and sample analysis ). The method and procedures shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

1) When the use of specific test methods for a sample analysis are mandated or requested, only those methods shall be used.

2) Where test methods are employed that are not required, as in the Performance Based Measurement System approach, the methods shall be fully documented and validated (see 5.10.2.1 and Appendix C), and be available to the client and other recipients of the relevant reports.

### 5.10.2.1 Demonstration of Capability

a) Prior to acceptance and institution of any test method, satisfactory demonstration of method capability is required. (See Appendix C and 5.6.2.b.) In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g., water, solids, biological tissue and air. In addition, for analytes which do not lend themselves to spiking, the demonstration of capability may be performed using quality control samples.

b) Thereafter, continuing demonstration of method performance, as per the quality control requirements in Appendix D (such as laboratory control samples) is required.

c) In all cases, the appropriate forms such as the Certification Statement (Appendix C) must be completed and retained by the laboratory to be made available upon request. All associated supporting data necessary to reproduce the analytical results summarized in the Certification Statement must be retained by the laboratory. (See Appendix C for Certification Statement.)

d) A demonstration of capability must be completed each time there is a significant change in instrument type, personnel, or test method.

e) In laboratories with a specialized work cell(s) (a group consisting of analysts with specifically defined tasks that together perform the test method), the group as a unit must meet the above criteria and this demonstration of capability must be fully documented.

f) When a work cell(s) is employed, and the members of the cell change, the new employee(s) must work with experienced analyst(s) in the specialty area and this new work cell must demonstrate acceptable performance through acceptable continuing performance checks (appropriate sections of Appendix D, such as laboratory control samples). Such performance must be documented and the four preparation batches following the change in personnel must not result in the failure of any batch acceptance criteria, e.g., method blank and laboratory control sample, or the demonstration of capability must be repeated. In addition, if the entire work cell is changed/replaced, the work cell must repeat the demonstration of capability (Appendix C).

g) When a work cell(s) is employed the performance of the group must be linked to the training record of the individual members of the work cell (see section 5.6.2).

### 5.10.3 Sample Aliquots

Where sampling (as in obtaining sample aliquots from a submitted sample) is carried out as part of the test method, the laboratory shall use documented procedures and appropriate techniques to obtain representative subsamples.

**5.10.4 Data Verification**

Calculations and data transfers shall be subject to appropriate checks.

a) The laboratory shall establish Standard Operating Procedure to ensure that the reported data are free from transcription and calculation errors.

b) The laboratory shall establish a Standard Operating Procedures to ensure that all quality control measures are reviewed, and evaluated before data are reported.

**5.10.5 Documentation and Labeling of Standards and Reagents**

Documented procedures shall exist for the purchase, reception and storage of consumable materials used for the technical operations of the laboratory.

a) The laboratory shall retain records for all standards including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if supplied), the date of receipt, recommended storage conditions, and an expiration date after which the material shall not be used unless it is verified by the laboratory.

b) Original containers (such as provided by the manufacturer or vendor) shall be labeled with an expiration date.

c) Records shall be maintained on reagent and standard preparation. These records shall indicate traceability to purchased stocks or neat compounds, reference to the method of preparation, date of preparation, expiration date and preparer's initials.

d) All containers of prepared reagents and standards must bear a unique identifier and expiration date and be linked to the documentation requirements in 5.10.5.c above.

**5.10.6 Computers and Electronic Data Related Requirements**

Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of test data, the laboratory shall ensure that:

a) all requirements of this Standard (i.e. Chapter Five) are met;
Sections 8.1 through 8.11 of the EPA Document 2185 - Good Automated Laboratory Practices (1995), shall be adopted as the standard for all laboratories employing microprocessors, computers, as well as laboratories employing Laboratory Information Management Systems.

b) computer software is documented and adequate for use;

c) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

d) computer and automated equipment are maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data; and,

e) it establishes and implements appropriate procedures for the maintenance of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

# Sample Handling, Sample Acceptance Policy and Sample Receipt;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>k) **procedures** for **handling submitted samples**;<br><br>g) the laboratory's procedures for achieving traceability of measurements; |

**5.11.1 Sample Tracking**

a) The laboratory shall have a documented system for uniquely identifying the items to be tested, to ensure that there can be no confusion regarding the identity of such items at any time. This system shall include identification for all samples, subsamples and subsequent extracts and/or digestates. The laboratory shall assign a unique identification (ID) code to each sample container received in the laboratory. The use of container shape, size or other physical characteristic, such as amber glass, or purple top, is not an acceptable means of identifying the sample.

b) This laboratory code shall maintain an unequivocal link with the unique field ID code assigned each container.

c) The laboratory ID code shall be placed on the sample container as a durable label.

d) The laboratory ID code shall be entered into the laboratory records (see 5.11.3.d) and shall be the link that associates the sample with related laboratory activities such as sample preparation or calibration.

e) In cases where the sample collector and analyst are the same individual or the laboratory preassigns numbers to sample containers, the laboratory ID code may be the same as the field ID code.

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**5.11.2 Sample Acceptance Policy**

The laboratory shall have a written sample acceptance policy that clearly outlines the circumstances under which samples will be accepted. Data from any samples which do not meet the following criteria must be flagged in an unambiguous manner clearly defining the nature and substance of the variation.

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### 5.11.2 Sample Acceptance Policy

This sample acceptance policy shall be made available to sample collection personnel and shall include, but is not limited to, the following areas of concern:

a) Proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample;

b) Proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink;

c) Use of appropriate sample containers;

d) Adherence to specified holding times;

e) Adequate sample volume. Sufficient sample volume must be available to perform the necessary tests; and

f) Procedures to be used when samples show signs of damage ,contamination or inadequate

### 5.11.3 Sample Receipt Protocols

a) Upon receipt, the condition of the sample, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. All items specified in 5.11.2 above shall be checked.

1) All samples which require thermal preservation shall be considered acceptable if the arrival temperature is either within +/-2 C of the required temperature or the method specified range. For samples with a specified temperature of 4 C, samples with a temperature ranging from just above the freezing temperature of water to 6 C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection may not meet this criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice.

2) The laboratory shall implement procedures for checking chemical preservation using readily available techniques, such as pH or free chlorine, prior to or during sample preparation or analysis.

b) The results of all checks shall be recorded.

**5.11.3 Sample Receipt Protocols**

c) Where there is any doubt as to the item's suitability for testing, where the sample does not conform to the description provided, or where the test required is not fully specified, the laboratory should consult the client for further instruction before proceeding. The laboratory shall establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

If the sample does not meet the sample receipt acceptance criteria listed in 5.11.3.a, 5.11.3.b or 5.11.3.c, the laboratory shall either:

1) Retain correspondence and/or records of conversations concerning the final disposition of rejected samples; or

2) Fully document any decision to proceed with the analysis of samples not meeting acceptance criteria.

i. The condition of these samples shall, at a minimum, be noted on the chain of custody or transmittal form and laboratory receipt documents.

ii. The analysis data shall be appropriately "qualified" on the final report.

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**5.11.3 Sample Receipt Protocols**

d) The laboratory shall utilize a permanent chronological record such as a log book or electronic database to document receipt of all sample containers.

1) This sample receipt log shall record the following:

i. Client/Project Name,
ii. Date and time of laboratory receipt,
iii. Unique laboratory ID code (see 5.11.1), and,
iv. Signature or initials of the person making the entries.

2) During the log-in process, the following information must be unequivocally linked to the log record or included as a part of the log. If such information is recorded/documented elsewhere, the records shall be part of the laboratory's permanent records, easily retrievable upon request and readily available to individuals who will process the sample. Note: the placement of the laboratory ID number on the sample container is not considered a permanent record.

i. The field ID code which identifies each container must be linked to the laboratory ID code in the sample receipt log.
ii. The date and time of sample collection must be linked to the sample container and to the date and time of receipt in the laboratory.
iii. The requested analyses (including applicable approved test method numbers) must be linked to the laboratory ID code.
iv. Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.

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**5.11.3 Sample Receipt Protocols**

e) All documentation, such as memos or transmittal forms, that is transmitted to the laboratory by the sample transmitter shall be retained.

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**5.11.3 Sample Receipt Protocols**

f) A complete chain of custody record (Section 5.12.4), if utilized, shall be maintained.

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**5.11.4 Storage Conditions**

The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, contamination, or damage to the sample during storage, handling, preparation, and testing; any relevant instructions provided with the item shall be followed.

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**5.11.4 Storage Conditions**

Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary.

a) Samples shall be stored according to the conditions specified by preservation protocols:

   1) Samples which require thermal preservation shall be stored under refrigeration which is +/-2 C of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4 C, storage at a temperature above the freezing point of water to 6 C shall be acceptable.

   2) Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.

b) Sample fractions, extracts, leachates and other sample preparation products shall be stored according to 5.11.4.a above or according to specifications in the test method.

c) Where a sample or portion of the sample is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

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**5.11.5 Sample Disposal**

The laboratory shall have standard operating procedures for the disposal of samples, digestates, leachates and extracts or other sample preparation products.

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# Records;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>d) **procedures** to ensure that all **records** required under this Chapter are **retaine**d, as well as procedures for control and maintenance of documentation through a **document control system** which ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force;<br><br>g) the laboratory's procedures for achieving **traceability of measurements**;<br><br>r) procedures for protecting **confidentiality** (including national security concerns), and proprietary rights;<br><br>s) procedures for audits and **data review**; |

**5.12 RECORDS**

The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. The system shall produce unequivocal, accurate records which document all laboratory activities. The laboratory shall retain on record all original observations, calculations and derived data, calibration records and a copy of the test report for a minimum of five years.

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**5.12 RECORDS**

There are two levels of sample handling: 1) sample tracking and 2) chain of custody, which is used for evidentiary or legal purposes. All essential requirements for sample tracking are outlined in Sections 5.12.1, 5.12.2 and 5.12.3. The basic requirements for chain of custody if required , by the data user or regulation , are specified in Section 5.12.4.

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**5.12.1 Record Keeping System and Design**

The record keeping system must allow historical reconstruction of all laboratory activities that produced the resultant sample analytical data. The history of the sample must be readily understood through the documentation. This shall include interlaboratory transfers of samples and/or extracts.

a) The records shall include the identity of personnel involved in sampling, sample receipt, preparation, calibration or testing.

b) All information relating to the laboratory facilities equipment, analytical test methods, and related laboratory activities, such as sample receipt, sample preparation, or data verification shall be documented.

c) The record keeping system shall facilitate the retrieval of all working files and archived records for inspection and verification purposes.

d) All documentation entries shall be signed or initialed by responsible staff. The reason for the signature or initials shall be clearly indicated in the records such as sampled by, prepared by, or reviewed by.

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### 5.12.1 Record Keeping System and Design

The record keeping system must allow historical reconstruction of all laboratory activities that produced the resultant sample analytical data. The history of the sample must be readily understood through the documentation. This shall include interlaboratory transfers of samples and/or extracts.

e) All generated data except those that are generated by automated data collection systems, shall be recorded directly, promptly and legibly in permanent ink.

f) Entries in records shall not be obliterated by methods such as erasures, overwritten files or markings. All corrections to record-keeping errors shall be made by one line marked through the error. The individual making the correction shall sign (or initial) and date the correction. These criteria also shall apply to electronically maintained records.

g) Refer to 5.10.6 for Computer and Electronic Data.

### 5.12.2 Records Management and Storage

a) All records (including those pertaining to calibration and test equipment), certificates and reports shall be safely stored, held secure and in confidence to the client. NELAC-related records shall be available to the accrediting authority.

b) All records, including those specified in 5.12.3 and 5.12.4, shall be retained for a minimum of five years from generation of the last entry in the records. All information necessary for the historical reconstruction of data must be maintained by the laboratory. Records which are stored only on electronic media must be supported by the hardware and software necessary for their retrieval.

c) Records that are stored or generated by computers or personal computers shall have hard copy or write-protected backup copies.

d) The laboratory shall establish a record management system for control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation storage and reporting.

e) Access to archived information shall be documented with an access log. These records shall be protected against fire, theft, loss, environmental deterioration, vermin and, in the case of electronic records, electronic or magnetic sources.

f) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients instructions (see 4.1.8.e) in the event that a laboratory transfers ownership or goes out of business. In addition, in cases of bankruptcy, appropriate regulatory and state legal requirements concerning laboratory records must be followed.

### 5.12.3 Laboratory Sample Tracking

#### 5.12.3.1 Sample Handling

A record of all procedures to which a sample is subjected while in the possession of the laboratory shall be maintained. These shall include but are not limited to all records pertaining to:

a) Sample preservation including appropriateness of sample container and compliance with holding time requirement;

b) Sample identification, receipt, acceptance or rejection and log-in;

c) Sample storage and tracking including shipping receipts, transmittal forms, and internal routing and assignment records; and

d) Sample preparation including cleanup and separation protocols, ID codes, volumes, weights, instrument printouts, meter readings, calculations, reagents;

e) Sample analysis;

f) Standard and reagent origin, receipt, preparation, and use;

g) Equipment receipt, use, operating conditions and preventative maintenance:

h) Calibration criteria, frequency and acceptance criteria;

I) Data and statistical calculations, review, confirmation, interpretation, assessment and reporting conventions;

j) Method performance criteria including expected quality control requirements.

k) Quality control protocols and assessment;

l) Electronic data security, software documentation and verification, software and hardware audits, backups, and records of any changes to automated data entries;

m) All automated sample processing systems; and

n) The laboratory shall have documented procedures for the receipt, retention or safe disposal of calibration or test items, including all provisions necessary to protect the integrity of the laboratory.

**5.12.3.2 Laboratory Support Activities**
In addition to documenting all the above-mentioned activities, the following shall be retained:

a) All original raw data, whether hard copy or electronic, for calibrations, samples and quality control measures, including analysts work sheets and data output records (chromatograms, strip charts, and other instrument response readout records);

b) A written description or reference to the specific test method used which includes a description of the specific computational steps used to translate parametric observations into a reportable analytical value;

c) Copies of final reports;

d) Archived standard operating procedures;

e) Correspondence relating to laboratory activities for a specific project;

f) All corrective action reports, audits and audit responses;

g) Proficiency test results and raw data; and,

h) Results of **data review**, verification, and cross-checking procedures.

**5.12.3.3 Analytical Records**
The essential information to be associated with analysis, such as strip charts, tabular printouts, computer data files, analytical notebooks, and run logs, shall include:

a) Laboratory sample ID code;

b) Date and time of analysis;

c) Instrumentation identification and instrument operating conditions/parameters (or reference to such data);

d) Analysis type;

e) All manual calculations; and,

f) Analyst's or operator's initials/signature.

**5.12.3.4 Administrative Records**
The following shall be maintained:

a) Personnel qualifications, experience and training records;

b) Records of demonstration of capability for each analyst; and

c) A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory record.

**5.12.4 Legal/Evidentiary Custody**

The use of chain of custody (COC) protocols are required by some State or federal programs. In addition to the records listed in 5.12.3 and the performance standards outlined in 5.12.1 and 5.12.2, the following protocols shall be used when COC is required of the organization for legal or evidentiary purposes.

**5.12.4 Legal/Evidentiary Custody**
**5.12.4.1 Basic Requirements**

The chain of custody records shall establish an intact, continuous record of the physical possession, storage and disposal of sample containers, collected samples, sample aliquots, and sample extracts or digestates. For ease of discussion, the above-mentioned items shall be referred to as samples:

a) A sample is in someone's custody if:

1) It is in one's actual physical possession;
2) It is in one's view, after being in one's physical possession;
3) It is in one's physical possession and then locked up so that no one can tamper with it;
4) It is kept in a secured area, restricted to authorized personnel only.

b) The COC records shall account for all time periods associated with the samples.

c) The COC records shall identify individuals who physically handled individual samples.

d) In order to simplify record-keeping, the number of people who physically handle the sample should be minimized. A designated sample custodian, who is responsible for receiving, storing and distributing samples is recommended.

e) The COC records are not limited to a single form or document. However, organizations should attempt to limit the number of documents that would be required to establish COC.

f) Chain of custody shall begin at the point established by the federal or State oversight program. This may begin at the point that cleaned sample containers are provided by the laboratory or the time sample collection occurs.

g) The COC forms shall remain with the samples during transport or shipment.

h) If shipping containers and/or individual sample containers are submitted with sample custody seals, and any seals are not intact, the lab shall note this on the chain of custody.

I) Mailed packages should be registered with return receipt requested. If packages are sent by common carrier, receipts should be retained as part of the permanent chain-of-custody documentation.

j) Once received by the laboratory, laboratory personnel are responsible for the care and custody of the sample and must be prepared to testify that the sample was in their possession and view or secured in the laboratory at all times from the moment it was received from the custodian until the time that the analyses are completed or the time of sample disposal.

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**5.12.4 Legal/Evidentiary Custody**
**5.12.4.2 Required Information in Custody Records**

In addition to the information specified in 5.11.1.a and 5.11.1.b, tracking records shall include, by direct entry or linkage to other records:

a) Time of day and calendar date of each transfer or handling procedure;

b) Signatures of all personnel who physically handle the sample(s);

c) All information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting; and

d) Common carrier documents.

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**5.12.4 Legal/Evidentiary Custody**
**5.12.4.3 Controlled Access to Samples**

Access to all legal samples and subsamples shall be controlled and documented.

a) A clean, dry, isolated room, building, and/or refrigerated space that can be securely locked from the outside must be designated as a custody room.

b) Where possible, distribution of samples to the analyst performing the analysis must be made by the custodian(s).

c) The laboratory area must be maintained as a secured area, restricted to authorized personnel only.

d) Once the sample analyses are completed, the unused portion of the sample, together with all identifying labels, must be returned to the custodian. The returned tagged sample must be retained in the custody room until permission to destroy the sample is received by the custodian or other authority.

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**5.12.4 Legal/Evidentiary Custody**
**5.12.4.4 Transfer of Samples to Another Party**

Transfer of samples, subsamples, digestates or extracts to another party are subject to all of the requirements for legal chain of custody.

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**5.12.4 Legal/Evidentiary Custody**
**5.12.4.4 Sample Disposal**

a) If the sample is part of litigation, disposal of the physical sample shall occur only with the concurrence of the affected legal authority, sample data user and/or submitter of the sample.

b) All conditions of disposal and all correspondence between all parties concerning the final disposition of the physical sample shall be recorded and retained.

c) Records shall indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility, or sample returned to client), and the name of the individual who performed the task.

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# Laboratory Report Format and Contents;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>v) reference to procedures for reporting analytical results; and,<br><br>p) the laboratory management arrangements for exceptionally permitting departures from documented policies and procedures or from standard specifications;<br><br>g) the laboratory's procedures for achieving traceability of measurements; |

**5.13 LABORATORY REPORT FORMAT AND CONTENTS**

The results of each test, or series of tests carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively. The results shall normally be reported in a test report and shall include all the information necessary for the interpretation of the test results and all information required by the method used. Some regulatory reporting requirements or formats such as monthly operating reports, may not require all items listed below, however, the laboratory shall provide all the required information to their client for use in preparing such regulatory reports.

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**5.13 LABORATORY REPORT FORMAT AND CONTENTS**

a) Except as discussed in 5.13.b, each report to an outside client shall include at least the following information (those prefaced with where relevant are not mandatory):

1) a title, e.g., "Test Report", or "Test Certificate", "Certificate of Results" or "Laboratory Results";

2) name and address of laboratory, and location where the test was carried out if different from the address of the laboratory and phone number with name of contact person for questions;

3) unique identification of the certificate or report (such as serial number) and of each page, and the total number of pages;

This requirement may be presented in several ways:

i. The total number of pages may be listed on the first page of the report as long as the subsequent pages are identified by the unique report identification and consecutive numbers, or

ii. Each page is identified with the unique report identification, the pages are identified as a number of the total report pages (example: 3 of 10, or 1 of 20).

Other methods of identifying the pages in the report may be acceptable as long as it is clear to the reader that discrete pages are associated with a specific report, and that the report contains a specified number of pages.

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**5.13 LABORATORY REPORT FORMAT AND CONTENTS**

a) Except as discussed in 5.13.b, each report to an outside client shall include at least the following information (those prefaced with where relevant are not mandatory):

4) name and address of client, where appropriate and project name if applicable;

5) description and unambiguous identification of the tested sample including the client identification code;

6) identification of test results derived from any sample that did not meet NELAC sample acceptance requirements such as improper container, holding time, or temperature;

7) date of receipt of sample, date and time of sample collection, date(s) of performance test, and time of sample preparation and/or analysis if the required holding time for either activity is less than or equal to 48 hours;

8) identification of the test method used, or unambiguous description of any non-standard method used;

9) if the laboratory collected the sample, reference to sampling procedure;

10) any deviations from (such as failed quality control), additions to or exclusions from the test method (such as environmental conditions), and any non-standard conditions that may have affected the quality of results, and including the use and definitions of data qualifiers;

11) measurements, examinations and derived results, supported by tables, graphs, sketches and photographs as appropriate, and any failures identified; identify whether data are calculated on a dry weight or wet weight basis; identify the reporting units such as µg/l or mg/kg; and for Whole Effluent Toxicity, identify the statistical package used to provide data;

12) when required, a **statement** of the **estimated uncertainty of the test result**;

13) a **signature** and **title**, or an equivalent electronic identification of the **person(s) accepting responsibility for the content of the certificate** or report (however produced), and **date of issue**;

14) at the laboratory's discretion, a **statement** to the effect that the **results relate only to the items tested or to the sample as received** by the laboratory;

15) at the laboratory's discretion, a **statement** that the certificate or **report shall not be reproduced except in full**, without the written approval of the laboratory;

16) clear **identification** of all test data provided by outside sources, such as **subcontracted laboratories**, clients, etc; and,

17) clear **identification** of numerical **results** with values **outside of quantitation levels**.

**5.13 LABORATORY REPORT FORMAT AND CONTENTS**

b) Laboratories that are operated by a facility and whose sole function is to provide data to the facility management for compliance purposes (in-house or captive laboratories) shall have all applicable information specified in 1 through 17 above readily available for review by the accrediting authority. However formal reports detailing the information are not required if:

1) The in-house laboratory is itself responsible for preparing the regulatory reports; or

2) The laboratory provides information to another individual within the organization for preparation of regulatory reports. The facility management must ensure that the appropriate report items are in the report to the regulatory authority if such information is required.

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**5.13 LABORATORY REPORT FORMAT AND CONTENTS**

c) Where the certificate or report contains results of tests performed by subcontractors, these results shall be clearly identified by subcontractor name or applicable accreditation number.

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**5.13 LABORATORY REPORT FORMAT AND CONTENTS**

d) After issuance of the report, the laboratory report shall remain unchanged. Material amendments to a calibration certificate, test report or test certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report or Test Certificate, serial number . . . [or as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of this Standard.

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**5.13 LABORATORY REPORT FORMAT AND CONTENTS**

e) The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any calibration certificate, test report or test certificate or amendment to a report or certificate.

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**5.13 LABORATORY REPORT FORMAT AND CONTENTS**

f) The laboratory shall ensure that, where clients require transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, staff will follow documented procedures that ensure that the requirements of this Standard are met and that confidentiality is preserved.

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**5.13 LABORATORY REPORT FORMAT AND CONTENTS**

g) Laboratories accredited to be in compliance with these standards shall certify that the test results meet all requirements of NELAC or provide reasons and/or justification if they do not.

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# Subcontracting Analytical Samples;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>v) reference to **procedures for reporting analytical results**; and,<br><br>g) the laboratory's procedures for achieving **traceability of measurements**; |

**5.14 SUBCONTRACTING ANALYTICAL SAMPLES**

a) The laboratory shall advise the client in writing of its intention to subcontract any portion of the testing to another party.

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**5.14 SUBCONTRACTING ANALYTICAL SAMPLES**

b) Where a laboratory subcontracts any part of the testing covered under NELAC, this work shall be placed with a laboratory accredited under NELAC for the tests to be performed.

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**5.14 SUBCONTRACTING ANALYTICAL SAMPLES**

c) The laboratory shall retain records demonstrating that the above requirements have been met.

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# Outside Support Services and Supplies;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>i) **mechanisms** for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and **resources** before commencing such work;<br><br>i) **reference** to the major equipment and reference measurement standards used as well as the facilities and **services** used by the laboratory in conducting tests;<br><br>g) the laboratory's procedures for achieving **traceability of measurements**; |

**5.15 OUTSIDE SUPPORT SERVICES AND SUPPLIES**

a) Where the laboratory procures outside services and supplies, other than those referred to in this Standard, in support of tests, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests.

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**5.15 OUTSIDE SUPPORT SERVICES AND SUPPLIES**

b) Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations or tests concerned.

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**5.15 OUTSIDE SUPPORT SERVICES AND SUPPLIES**

c) The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for tests.

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# Complaints;

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| | **5.5.2 Quality Manual**<br>The quality manual and related quality documentation shall also contain:<br><br>q) procedures for dealing with **complaints**; |

**5.16 COMPLAINTS**

The laboratory shall have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the requirements of this Standard or otherwise concerning the quality of the laboratory's calibrations or tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited in accordance with Section 5.5.3.1. Records of the complaint and subsequent actions shall be maintained.